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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,544	10/17/2001	Ira G. Schulman	509132000100	7779

20350 7590 04/20/2004

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EXAMINER	
KAM, CHIH MIN	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/982,544	SCHULMAN ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 4/6/04 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: *16 and 23*.

   Claim(s) rejected: *13,16,17,21-23,30,31,34 and 36*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☒ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). *6/20/03*.

10. ☐ Other: _____

christopher S. F. Low

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
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Continuation of 2. NOTE: The amendment to the claims does not resolve the current issues under 35 USC 112, first paragraph. In the amendment of April 6, 2004, claims 16 and 23 have been amended. Applicants' response has been fully considered, however, claims 13, 16, 17, 21-23, 30, 31, 34 and 36 are rejected under 35 USC 112, first paragraph.

If applicants' amendment were entered, it would have the following response:

1. Claims 13, 16, 17, 21-23, 30, 31, 34 and 36 are rejected under 35 USC 112, first paragraph, because the specification, while being enabling for a method of treating diabetes type II comprising administering a specific LXR agonist, compound 1 (structure shown at page 30, paragraph 0105), does not reasonably provide enablement for a method for treating, or reducing the risk of developing or recurrence of diabetes, or treating type II diabetes comprising administering an LXR agonist, wherein the structure of the LXR agonist is not defined. The specification does not enable a person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims because the specification only indicates the treatment of wild type mice with a specific pan-LXR agonist, compound 1 results in significant increase in high density lipoprotein (HDL, paragraph 0109, Fig 5) and compound 1 can reduce hyperglycemia (elevated blood glucose) in the diabetic mice (pages 38-39, paragraphs 0121-0122, Fig. 15), however, it does not demonstrate the effects of various LXR agonists in the treatment of diabetes or type II diabetes as encompassed by the claims. Moreover, the specification has not shown the treating conditions for reducing the risk of developing or the risk of recurrence of diabetes using an LXR agonist. There are no working examples indicating the claimed methods using various LXR agonists which have different structures. Furthermore, the specification does not provide any specific guidance as to how to monitor reducing the risk of developing or the risk of recurrence of diabetes, for example, the dosage, the time of the treatment and how the effect of the compound on diabetes being monitored if the disease is still developing. Since the specification fails to provide sufficient teachings on the use of various LXR agonists, and how to monitor reducing the risk of developing or the risk of recurrence of diabetes diabetes, it is necessary to have additional guidance and to carry out further experimentation to assess the effects of various LXR agonists in the treatment. In response, applicants indicate the specification provides an enabling disclosure and working examples showing in vivo animal model and in vitro data that is direct relevance to the claimed methods, e.g., paragraph [0121] and Fig. 15 for a pan LXR agonist, compound 1; one LXR agonist is disclosed in the specification does not necessarily render the specification non-enabled, and there must be objective reasons why undue experimentation is necessary to make and use the claimed invention; other LXR agonists are known in the literature and available for use in the claimed method without undue experiments; and Examiner has not stated why one example cannot extrapolate the specifically disclosed LXR agonist across the entire scope of the claims cover the genus of LXR agonists. Applicant further assert the current pending claims are fully enabled by the specification and do not require undue experimentation based on the reasoning to the factors presented in In re Wands (pages 8-17 of the response). The response has been fully considered, however, the argument is not found persuasive because the specification only describes using a specific LXR agonist (compound 1, a sulfonamide) to treat diabetes, it does not disclose the treating conditions such as the dose for other LXR agonists containing different structures (e.g., oxysterol derivatives and TOFA) in the treatment of diabetes, since they have different structures, the doses and effects of these various LXR agonists in treating diabetes requires further experimentation. Moreover, the specification (paragraph [0009]) also indicates LXR agonists produce significant increases in the level of serum triglycerides, and high levels of serum triglycerides are known to increase the risk of cardiovascular diseases and other metabolic diseases, thus it is necessary to carry out further experimentation to assess the effect of an LXR agonist in affecting triglyceride level and in the treatment of diabetes. Furthermore, the specification does not teach how to reduce the risk of developing or the risk of recurrence of diabetes using an LXR agonist. Moreover, the claimed method encompasses the use of unspecified LXR agonists, where the correlation of structures and activities of the LXR agonists are not described in the specification, thus their effects in the treating diabetes are not predictable, thus, as indicated in the section above, it requires undue experimentation to enable the full scope of the claims.

Continuation of 5. does NOT place the application in condition for allowance because: The amendment to the claims does not resolve current issue under 35 USC 112, first paragraph for claims 13,16,17,21-23,30,31,34 and 36 .

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. CMK
Patent Examiner

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April 16, 2004